

Please amend the claims as follows:

Sub 17
2. [Amended] The method of claim 15, wherein the target protein is a protein that is expressed in malignant cells in an animal.

3. [Amended] The method of claim 2, wherein the target protein is Her-2/*neu*, Her-3, Her-4, estrogen receptor, prostate-specific antigen, Epidermal Growth Factor Receptor ("EGFR"), AKT, p13 kinase or Mitogen-Activated Protein Kinase ("MAP kinase").

4. [Amended] The method of claim 15, wherein the plurality of control cell pellets are prepared from cultured cell lines.

5. [Amended] The method of claim 4, wherein the cultured cell lines express a reproducible amount of the target protein.

6. [Amended] The method of claim 15, wherein the quantity of said target protein from each of the control cell pellets is determined using an immunological reagent.

7. [Amended] The method of claim 6, wherein the quantity of said target protein from each of the control cell pellets is determined by Enzyme Linked Immunosorbent Assay ("ELISA").

8. [Amended] The method of claim 15, wherein the quantity of said target protein from each of the control cell pellets is normalized to the total amount of protein in the cell pellet.

9. [Amended] The method of claim 8, wherein the quantity of said target protein from each of the control cell pellets is normalized to the total amount of protein per cell.

Q1
10. [Amended] The method of claim 8, wherein the quantity of said target protein in the calibration curve is expressed as number of target protein molecules per cell.

Sub B1
11. [Amended] The method of claim 15, wherein the average optical density of the target protein-specific staining is determined using image analysis.

12. [Amended] The method of claim 11, wherein said biological sample is stained with a multiplicity of stains, and wherein the image analysis is performed by splitting a signal comprising an optical density of the stained target protein in said biological sample into a multiplicity of signals that are processed using optical filters having different absorption and transmittance properties, so that each signal is specific for one of said multiplicity of stains used to stain the cells in the biological sample.

Q1/c
13. [Amended] The method of claim 15, wherein the detectable label is a chromogen or a fluorophore.

Please add the following new claims:

Sub B1
15. A method for determining the quantity of a target protein in a biological sample comprising a cell, the method comprising the steps of:

(a) determining the quantity of said target protein in a plurality of control cell pellets, wherein said quantity is determined in a first portion from each of the control cell pellets, and wherein the quantity of the target protein from each of the control cell pellets is not the same;

(b) immunohistochemically staining said target protein in a second portion from each of the control cell pellets using a detectably labeled antibody directed against said target protein;

Q2
(c) determining an average optical density of ^{stained} target protein-specific staining ^{per pixel of sample} in the second portion from each of the control cell pellets;

(d) generating a calibration curve relating said quantity of said target protein as determined in (a) with said average optical density of target protein-specific staining as determined in (c) for the plurality of control cell pellets;

Sub B1
(e) immunohistochemically staining said target protein from a portion of cells from said biological sample using said detectably labeled antibody directed against said target protein;

(f) determining an average optical density of target protein-specific staining in said portion of cells from said biological sample;

(g) determining the quantity of said target protein in said biological sample by comparing the average optical density of target protein-specific staining as determined in step (f) in said portion of cells from said biological sample to the calibration curve as generated in step (d), wherein the quantity of said target protein is derived from the calibration curve.

will cancel
16. The method of claim 15, wherein said biological sample is a tissue or cell sample removed from a subject.

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17. The method of claim 15, wherein the plurality of control cell pellets are not embedded in paraffin.

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18. The method of claim 15, wherein the plurality of control cell pellets are not immobilized in a hydrophilic matrix.

Q2 cont
19. The method of claim 15, wherein the calibration curve is linear.

20. The method of claim 15, wherein the immunohistochemically staining of (e) is performed with the same reagents as is used for the immunohistochemically staining of (b).

In the Specification:

Please replace Figures 2, 3, and 6 with replacement Figures 2, 3, and 6. Replacement Figures 2, 3, and 6 are attached as Appendix D.